

Letters to the Editor

Improving Procedural Times During Percutaneous Atrial Septal Defect Closure

We read with interest the expedited review by Jones et al. (1) which details multicenter experience with the Helex Septal Occluder device (W. L. Gore and Associates, Flagstaff, Arizona) for the percutaneous closure of secundum atrial septal defects (ASD). The investigators report a favorable experience with the device relative to surgical closure in terms of length of hospital stay and duration of anesthesia, with equivalence in the primary end point of the study, which was "clinical success." At Oxford we have used the Helex device for over 3 years for both patent foramen ovale (PFO) and ASD closures with 2 dedicated operators. Since June 2006 we have used the Helex device to close secundum ASDs in 38 patients successfully with no significant adverse events. A key point of difference is the markedly lower procedural time and fluoroscopy time in our cohort compared with the reported study (average fluoroscopic time 7.4 vs. 28 min, respectively; total time under anesthesia 49.4 vs. 160 min, respectively). In fact, our low fluoroscopy times have enabled us to close PFOs using the Helex device rapidly and safely in pregnancy (2).

It is unclear why this difference is apparent. We now routinely use intracardiac echocardiography (ICE) during the procedure, which has resulted in a reduction in procedural time by avoiding the need for general anesthesia, which is often required if transesophageal echocardiography is used, and has allowed same-day discharge of these patients. The proportion of patients in the reported study that underwent the procedure with adjunctive ICE is not reported, and whether this is a factor in the disparity observed in both procedural and fluoroscopy times is not known but could indeed play a role. Certainly, our single-center dedicated-operator experience using ICE to close secundum ASDs with the Helex device has yielded low procedural and fluoroscopy times with excellent results and no significant adverse events. In centers using this device, operator familiarity and ICE could help in optimizing procedural times.

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2. Schrale RG, Ormerod J, Ormerod OJ. Percutaneous device closure of the patent foramen ovale during pregnancy. *Catheter Cardiovasc Interv* 2007;69:579-83.

Reply

We appreciate the interest by Drs. Bhindi and Ormerod who comment favorably on our paper, "Results of the Multicenter Pivotal Study of the Helex Septal Occluder for Percutaneous Closure of Secundum Atrial Septal Defects," recently published in the *Journal* (1). They report their own successful experience with the use of the Helex Septal Occluder in 38 patients with atrial septal defect (ASD) at the John Radcliffe Hospital in Oxford, United Kingdom. They go on to draw a distinction between the procedural and fluoroscopic time in their own experience versus what was reported in our paper. Furthermore, they speculate that some of this difference could be due to their routine use of intracardiac echocardiography (ICE) instead of transesophageal echocardiography.

There are several factors that likely contributed to the differences in procedural and fluoroscopic time reported in their experience and our multicenter trial. Our pivotal trial represented some of the earliest human experience with this technique when best clinical practices were being first defined. All of our subjects were being treated for ASD, and most of them were children. Some of those ASDs proved to be relatively large for this device design (18 to 20 mm). Occasionally, the investigators made several attempts with multiple devices to close these larger defects. This additional effort accounted for the wide range of fluoroscopy time reported in our series, 6 min to 148 min. This is why we chose to report the median fluoroscopy time of 22 min rather than the mean time of 28 min, believing it more accurately represented the experience of the majority of our subjects. Furthermore, a complete hemodynamic study was a protocol requirement that took time to perform. Drs. Bhindi and Ormerod do not comment on their use of defect balloon sizing in selecting proper size device, a time-consuming but not universally practiced technique. Balloon sizing in our study was another protocol-specified step that could further account for the time differences. Finally, the Helex delivery system available in Europe for several years, version 1.5, is much simpler and faster to use. The older 1.0 version used in our trial is still the only approved delivery system available in the U.S.

We do agree with Drs. Bhindi and Ormerod that the routine use of ICE, at the time unavailable for the vast majority of our subjects, has the effect of significantly reducing anesthesia time and improving patient comfort by eliminating the requirement for general endotracheal anesthesia. The impact of the use of ICE on fluoroscopy time, however, is less certain and more likely related to the other factors stated. We believe the biggest drawback to the

wide acceptance of ICE in much of the world remains the cost of the imaging catheter. We look forward to improvements in design and manufacturing technology that bring down the cost of this useful modality so that it is affordable for all.

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